In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 16-1083V

(to be published)

J.S.,	*	
	*	Filed: July 15, 2022
	*	
	*	Chief Special Master Corcoran
Petitioner,	*	
	*	
v.	*	Human Papillomavirus Vaccine;
	*	Hepatitis A Vaccine;
SECRETARY OF HEALTH	*	Postural Orthostatic
AND HUMAN SERVICES,	*	Tachycardia Syndrome;
	*	Reliable Theory
Respondent.	*	Cognizable Injury
	*	

Robert J. Krakow, Law Office of Robert J. Krakow, New York, NY, for Petitioner.

Kimberly S. Davey, U.S. Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

On August 30, 2016, J.S. filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioner alleges that she suffered from "inappropriate tachycardia" and autonomic dysfunction, manifesting in a wide variety of conditions and symptoms (including joint pain, dizziness, nausea, and postural orthostatic tachycardia syndrome ("POTS")), after receipt of the human papillomavirus ("HPV") and Hepatitis A ("Hep. A") vaccines on August 4 and 19, 2015. *Id.* at 1. After the filing of

[1] This Decision will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "The Program" or "Program"]. Individual section references hereafter will be to Section 300aa of the Act.

multiple expert reports, I set a schedule to rule on the record, and the matter is now fully briefed. Petitioner's Motion, filed Dec. 6, 2021 (ECF No. 105) ("Mot."); Respondent's Opposition Brief, filed Jan. 19, 2022 (ECF No. 106) ("Opp."); Petitioner's Reply Brief, filed Feb. 2, 2022 (ECF No. 108) ("Reply").

Collectively the parties have filed ten expert reports, offering competing takes on a causation theory alleging that the HPV and Hep. A vaccines can stimulate the production of autoantibodies that could be causal of autonomic dysfunction, primarily manifesting as orthostatic intolerance. But the claim fails on a more fundamental matter: Petitioner has not shown, on the basis of this medical record, that she experienced *any* arguably vaccine-caused disease or condition—and it is more likely her symptoms reflect somatization. Dismissal is therefore appropriate even without considering the strength of Petitioner's "can cause" showing—although that too was inadequate, given the science suggesting that "dysautonomia" is generally not autoimmune in character, and not otherwise likely capable of being vaccine-induced.

I. Factual Background

Pre-Vaccination History

Petitioner was born on March 3, 1997—and was thus 18 years old when she received the vaccines at issue. Ex. 2 at 1. Her pre-vaccination history records three notable events. First, she saw a cardiologist in June 2008 for episodes of shortness of breath and difficulty breathing while swimming, but her symptoms were later attributed to asthma. *Id.* at 58–61. Second, she underwent a head MRI on October 1, 2008, for occipital migraines, which showed evidence for sinusitis, but was otherwise normal. *Id*. at 55–56. Finally, in March 2012 she was evaluated by an endocrinologist for autoimmune thyroid disease. Ex. 15 at 1–2. At that time, she tested positive for antibodies relevant to the disease, but was not yet symptomatic, although she did report joint aches and ongoing abdominal complaints. *Id.*

Vaccinations and Initial ER Visits

On August 4, 2015, at a well exam J.S. received the Hep. A and pneumococcal vaccines. Ex. 3 at 30–35. Her examination was normal, apart from a functional heart murmur. *Id*. Two weeks later, she traveled to Nicaragua with her family from August 10-16, 2015. Ex. 4 at 1. Other than experiencing a minor bacterial skin infection on her elbow after the trip, the records reveal no reaction to this initial vaccination. Ex. 20 at 12. A few days later (August 19, 2015), Petitioner received an influenza vaccine and the first dose of the HPV vaccine. Ex. 3 at 20, 36, 106. No immediate reaction to vaccine administration was noted.

Beginning the next day, however, J.S. began experiencing a series of emergency treatment interventions culminating in a hospital stay that same month. First, she was transported by ambulance on August 20, 2015, to Riverview Medical Center in Red Bank, New Jersey, complaining of anxiety, hyperventilation, and a panic attack. Ex. 7 at 211–13. There, Petitioner reported circumstances that were possibly relevant to her sudden symptoms: she was leaving for college the next day, had broken up with her boyfriend,[3] and also indicated that she had been feeling sad recently. Ex. 7 at 224, 226–27, 233. A review of systems revealed fatigue, shortness of breath, anxiety and depression, and she was tachycardic, but otherwise the exam yielded normal results. *Id*. at 224. Upon discharge Petitioner was assessed with an anxiety reaction and hyperventilation, and was instructed to follow-up with psychiatry within twenty-four hours. *Id*. at 223, 233–36.

Second, Petitioner returned (also by ambulance) to the emergency room the following day (August 21), again due to anxiety. Ex. 7 at 180–81. A complete blood panel, metabolic panel, toxicology screen, and pregnancy test were negative or resulted in findings deemed noncontributory. *Id.* at 182–84. After receiving a dose of Ativan, J.S. was discharged with a diagnosis of anxiety. *Id*. at 188–90. Finally, Petitioner was transported via ambulance back to the emergency room a third time, on August 22, 2015, where she was noted to be awake, anxious, and making jerking movements. Ex. 6 at 57, 72.

Petitioner was transferred to a hospital able to provide a higher level of care for further evaluation of her twitching symptoms before being admitted to Jersey Shore Hospital that very day. Ex. 3 at 24–27. She now reported a three-day history of tonic-clonic jerking movements, lasting twenty to forty minutes each and involving all four extremities (although the records from her treatment events discussed above do not corroborate this contention),[4] along with hyperventilation. Ex. 6 at 77–80. Reference was also again made to Petitioner's recent trip out of the country and her skin infection *Id.* at 77. Initial treater impressions were that Petitioner had experienced pseudoseizures[5] vs. "new onset seizure disorder." *Id.* at 80.

[3] Petitioner has disputed the accuracy of this particular fact. *See e.g.*, Mot. at 6 n.5. I do not resolve this issue, however, since its disposition does not alter my overall conclusion or determination that vaccination did not likely cause the Petitioner's symptoms.

[4] In fact, this record makes no mention of Petitioner's ER visits days before. Ex 6 at 77 ("ER only (not admitted) for MVA *3 months ago*") (emphasis added).

[5] A pseudoseizure is "an attack resembling an epileptic seizure but being a type of conversion disorder; it lacks the electroencephalographic characteristics of epilepsy and the patient may be able to stop it by an act of will." *Pseudoseizure,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111236 (last visited July 14, 2022).

Initial Efforts to Diagnose Etiology for Petitioner's Symptoms

During the period of J.S.'s hospitalization (which occurred in the days and month immediately after receipt of the HPV vaccine), treaters attempted to identify the nature and cause of her symptoms. Although these treaters took note of the fact that Petitioner had recently received the HPV vaccine, the record suggests an initial view that her symptoms had a mostly psychologic character.

Thus, a video EEG conducted on August 23-24, 2015, was normal—even though Petitioner was experiencing jerking episodes, they were not accompanied by any abnormal electrical discharge. Ex. 6 at 92. Petitioner also underwent consultations for infectious diseases and was examined by a neurologist. *Id.* at 33–38. The physicians noted her recent vaccinations, as well as her trip to Nicaragua, a family history of autoimmune issues (including a grandmother with myasthenia gravis), and a history of "migraines presenting with jerking movements after receiving her Gardasil vaccine." *Id*. at 38. One treater specifically observed the temporal association with J.S.'s receipt of the first HPV dose, and even wondered whether she may have had an adverse reaction, but felt that her symptoms would resolve with time. *Id*. at 35. The neurologist who reviewed Petitioner's presentation (relying on her self-reported symptoms as well as her recent vaccination history) had the impression "unlikely myoclonic seizure," and included in the differential PANDAS[6] as well as an acute anxiety disorder, although he noted the need to "[r]ule out reaction to Gardasil vaccine." *Id*. at 38.

At the same time as the above encounters, Petitioner also saw a psychiatrist while an in-patient at Jersey Shore Hospital. Ex. 6 at 40–42. The history taken by the psychiatrist took into account J.S.'s repeated ER visits in the days before her hospitalization, noting as well that "the video EEG has shown that she has not had any seizure-like activity." *Id.* at 40. The psychiatrist diagnosed Petitioner with a panic attack and recommended that she begin therapy after starting college (although she also noted the need to rule out a possible vaccine reaction or neurologic issue). *Id*. at 42. The hospital's pediatric attending doctor also saw petitioner on August 24, 2015, opining that her episodes were unlikely to have a cardiac etiology, as she had a normal EEG and normal MRIs with and without contrast. *Id*. at 130, 134. Taking all the above into account (including the already-mentioned treater speculation of a possible vaccine connection—speculation that was not ultimately substantiated), J.S. was discharged home on August 27, 2015, with a diagnosis of "anxiety based events *not related to vaccine*." Ex. 6 at 131 (emphasis added).

On September 2, 2015, J.S. saw Dr. John Wells, a neurologist at NYU, for an additional evaluation. Ex. 21 at 1–6. Dr. Wells noted Petitioner's recent medical history, recording that on August 20th she had experienced "prolonged tachycardia," with two more days of similar events

[6] "PANDAS" stands for Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcus infections. *Bains v. Sec'y of Health & Hum. Servs.*, No. 18-1212V, 2019 WL 4121084, at *1 (Fed. Cl. Spec. Mstr. July 26, 2019).

that resulted in ER visits. *Id.* at 3. He also reviewed a video of one of her "episodes," which had been recorded by her mother on a smart phone while she was at the Jersey Shore Hospital, but indicated he could not draw conclusions from it, noting as well that Petitioner's mother had speculated the HPV vaccine could have somehow triggered the episodes. *Id*. at 4. He also observed intermittent jerks during the visit itself of "unclear nature," but considered the normal EEG and MRIs from her hospitalization as unsupportive of a neurologic issue. *Id*. at 3–4.

Dr. Wells noted no other complaints or issues that could be contributory. Ex. 6 at 4. He ultimately proposed that Petitioner's episodes were "primarily anxiety based," and deemed it "unlikely" that they were caused by her HPV vaccination. Ex. 6 at 4. Consistent with the proposed diagnosis, Dr. Wells recommended counseling and encouraged Petitioner to avoid excessive supplements. *Id*.

Further Instances of Alleged Vaccine-Caused Symptoms

Even after initial analyses pointed in the direction of a psychological explanation, Petitioner continued to experience similar symptoms—and to inform treaters of her view that they were vaccine-associated.

On September 12, 2015, J.S. (who had now begun college in Providence, Rhode Island) presented to the emergency room at Rhode Island Hospital, accompanied by her mother. Ex. 5 at 3–4. She reported shaking, tremor episodes, and myoclonic jerks since receiving the HPV vaccination three weeks earlier, adding that her symptoms increased with loud noises or when she was startled or scared. *Id*. It was also stated that joint pain and concerns about them "locking up" had prompted Petitioner and her family to seek emergency treatment. *Id*. An EEG was negative, however, with a normal exam, and a psychologist who evaluated Petitioner expressed the view that her symptoms might be anxiety related. *Id*. at 5. Petitioner was thus discharged.

Five days later, on September 17, 2015, Petitioner presented to Riverview Medical Center[7] complaining of recurrent tonic-clonic jerking movements, and she was subsequently transferred to Cornell/New York Presbyterian Hospital on September 18, 2015. Ex. 7 at 170–71; Ex. 8 at 5. Petitioner's parents (who provided the medical history) again proposed to treaters that J.S.'s symptoms had begun after her receipt of the HPV vaccine, although the treater intake record also noted that prior ER-related workups had proposed anxiety as the explanation. Ex. 7 at 89. An initial exam was unremarkable and identified no notable cardiac abnormalities (although pulse was elevated), with a full neurologic exam not possible because Petitioner was either sleeping or unwilling to answer questions. *Id.* at 90.

A subsequent neurology consult resulted in the proposal that Petitioner was in fact only

[7] It appears Petitioner returned home from college by this time, in part if not wholly due to her symptoms. Ex. 7 at 90.

experiencing pseudoseizures and panic attacks. Ex. 7 at 89–90, 127; *see also* Ex. 9 at 25. Laboratory testing and an EKG were also (again) normal. Ex. 7 at 73–77. Treaters proposed that Petitioner's symptoms were probably pseudo-seizures attributable to stress-related psycho-somatization, with "the likelihood of her having some postvaccine [sic] complication causing seizures . . . to be less likely," *Id.* at 66–67. However, it was agreed that further medical evaluation was warranted, and treaters continued to take note of the vaccinations Petitioner had recently received. Ex. 8 at 5.

While at Cornell, J.S. underwent another video EEG on September 20-22, 2015. The EEG captured one shaking episode, but it was characterized as a psychogenic, non-epileptic seizure or "pseudoseizure," with no EEG correlate to suggest the contrary. Ex. 9 at 64–65, 67–68. Accordingly, the EEG study was deemed to produce normal results, with further study unnecessary, and Petitioner was "cleared from a neurologic perspective." *Id*. at 66. A pediatric resident note commented on petitioner's concerns that some of her symptoms began within twenty-four hours of the HPV vaccination, noting that "most likely this is not the underlying etiology." *Id*. at 58. A neurologist counseled petitioner's mother regarding the "high quality studies" that "refute an association between HPV vaccine and autoimmune events." *Id*. at 70. An extensive autoimmune work-up was negative, including normal IgA levels. Id. at 136–41. Petitioner and her mother initially refused discharge, but eventually agreed after speaking to the neurologist at length. *Id*. at 71. Petitioner was encouraged to give the therapeutic intervention from psychiatry a chance, as her doctors felt that there was an "underlying subconscious stressor" causing these episodes. *Id*. Petitioner was discharged on September 22, 2015. *Id*. at 67, 70.

Suggestions of Autoimmune Processes

The following month, Petitioner's efforts to identify the cause of her maladies began to find some support consistent with her claims herein—although, and as discussed below, these record items are reasonably weighed against the more substantial amounts of evidence undercutting these speculative proposals—much of which was generated more contemporaneously with the relevant vaccination event.

For example, Petitioner saw a cardiologist, Dr. David Lefkowitz, on October 2, 2015, informing him she had experienced a post-HPV vaccine "reaction." Ex. 3 at 92–95. Dr. Lefkowitz was informed that Petitioner's heart rate had soared to 160 bpm after receipt of the HPV vaccine, although it was also noted that her subsequent cardiac and neurologic workups had not identified seizure activity or other issues. *Id.* at 92. A "sit-stand" orthostatic test conducted in connection with this visit to Dr. Lefkowitz revealed an increase in heart rate from sitting to standing (62 bpm to 99 bpm), but no comparable change in blood pressure. *Id.* at 93.

Based upon what appears to be an overall cursory exam, Dr. Lefkowitz diagnosed

Petitioner with Shy-Drager syndrome,[8] along with apparent generalized autonomic dysfunction resulting in "inappropriate sinus tachycardia," due either to "a reaction to her various vaccines that occurred at the same time, or possibly based on a viral syndrome that she acquired while traveling through the jungles of Central America." Ex. 3 at 93, 84. He added, however, that her condition, whatever the etiology, was likely to prove self-limiting, and noted as well that EEG and EKG testing results had not suggested any underlying physiologic issue. *Id.* at 94.

Two weeks later, on October 13, 2015, J.S. saw an infectious disease and pulmonary specialist, Dr. Thomas Nash, who took a detailed history and conducted a physical examination. Ex. 4 at 1–3. Dr. Nash echoed the determinations of prior treaters that a degree of panic or anxiety might explain her symptoms, but also opined that her complaints went "well beyond what one would expect from straightforward panic/anxiety reaction," adding the possibility that "she has a degree of autoimmune encephalopathy provoked by immunizations in a susceptible patient with an autoimmune predisposition." *Id*. At the same time, however, Dr. Nash noted that J.S. displayed only "minor orthostatic changes which are not consistent with POTS or significant autonomic instability." *Id.* at 3. Dr. Nash recommended a blood work-up for inflammation and infection, a repeat MRI with contrast, echocardiogram, an evaluation for autoimmune encephalitis, and possible PET scan, lumbar puncture, and cerebral spinal fluid studies for recurrent seizure-like activities. *Id.*

The testing that was proposed, however, did not largely corroborate the presence of an autoimmune condition or autonomic dysfunction—let alone any larger concerns. For example, a brain MRI conducted on October 19, 2015, showed some nonspecific signal hyperintensity that could be evidence of white matter disease "associated with migraine headaches, vasculopathy, toxins, prior trauma, or prior inflammatory diseases," but which could not be fully identified as significant (although the lesions observed were deemed uncommon for someone of Petitioner's age). Ex. 4 at 7.

Petitioner next underwent a "tilt table" test often used to diagnose POTS[9] on November 18, 2015, that was performed by neurology specialists in dysautonomia. Ex. 18 at 1–3. But the test did not confirm POTS, showing instead "preserved cardiovascular autonomic reflexes with

[8] As noted in Respondent's brief, Shy-Drager syndrome is another term for multiple system atrophy ("MSA")—"a rare, degenerative neurological disorder affecting your body's involuntary (autonomic) functions, including blood pressure, breathing, bladder function and motor control." It shares many Parkinson's disease-like symptoms, such as slow movement, rigid muscles, and poor balance. Symptoms typically develop in adulthood, usually in the 50s or 60s. MSA progresses gradually, and eventually leads to death." Opp. at 8 n.6.

[9] The standard tilt table test entails the patient remaining in a supine position on an adjustable table for twenty minutes, followed by ten minutes tilted upright, with the heart rate and blood pressure measured minute by minute, to detect changes as position is altered. *Yalacki v. Sec'y of Health & Hum. Servs.*, No. 14-278V, 2019 WL 1061429, at *40 n.10 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), *mot. for review den'd,* 146 Fed. Cl. 80 (2019).

no evidence of orthostatic hypotension."[10] *Id.* at 3. It was also noted that the panel testing for autoimmune-associated antibodies revealed no abnormal antibodies present. *Id.* Her neurologic examination was otherwise normal. *Id*. at 3. At worst, it was noted that "[d]uring the head-up tilt position [Petitioner] had an episode of bilateral convulsive movements" but that "[t]he semiology of this laboratory-observed episode as well as her previous episodes are consistent with non-epileptic seizures." *Id*. In fact, testing for circulating epinephrine[11] performed during the test revealed a "marked increase" that the testing treaters deemed consistent with a panic disorder, and the episode of convulsive movements she displayed when in the "heads up" position of the test. *Id.* J.S. was encouraged to utilize cognitive behavioral therapy, including yoga and breathing exercises, to improve her symptoms, and a beta-blocker was recommended to help manage her stress levels. *Id.*

At the end of November 2015, Petitioner had a follow-up visit with Dr. Lefkowitz, now reporting that she felt better overall, and was much less "orthostatic," without palpitations, dizziness, or tremors. Ex. 3 at 97–98. Dr. Lefkowitz noted, however, that Petitioner's mother had done research and found a large number of POTS cases after the HPV vaccine. *Id*. Dr. Lefkowitz reiterated his prior diagnosis of Shy-Drager syndrome, despite the fact that J.S. was overall much improved clinically and asymptomatic. *Id.*

Even though Petitioner had started to report improvement in how she felt, she ended 2015 with more hospitalizations. On December 5, 2015, she was admitted to Robert Wood Johnson University Hospital in New Brunswick, New Jersey, for "convulsions." Ex. 11 at 2. It was again reported that Petitioner had started to experience symptoms in association with her receipt of an HPV vaccine dose. *Id.* at 68. Her mother also claimed that Petitioner had been diagnosed with possible autonomic dysfunction due to the Gardasil vaccine (presumably by Dr. Lefkowitz), and that she had undergone a tilt table test (although she reported the results to be "pending"). *Id*.[12] An EKG showed sinus tachycardia, but several basic lab studies were normal, and Petitioner was ultimately discharged. *Id*. at 8–10; 52–55.

A few days later, Petitioner went to the Monmouth Medical Center ER on December 9, 2015, based on a two-day history of aches and a sore throat. Ex. 3 at 88–91. Petitioner's mother now reported that she had a "history of POTS" (despite the negative tilt-table test), and that she

[10] The tilt table test did show repeated measures reflecting a pules rise of over 30, and once over 40 beats per minute. Ex. 18 at 3. However, the evaluation still did not conclude that Petitioner suffered from POTS. *Id.*

[11] Epinephrine is a hormone released by the adrenal glands in response to stress. *Epinephrine*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=16892&searchterm=epinephrine (last visited July 14, 2022).

[12] The record of the tilt table test filed in this case suggests its results had been obtained nearly three weeks before this hospitalization incident, although it is also possible they had not yet been provided to Petitioner or her family. *See generally* Ex. 18.

had suffered from a variety of symptoms after her HPV vaccine. *Id.* at 88. But her blood pressure, pulse, and an EKG were all normal, as was a cardiac monitor, resulting in her discharge (with advice to follow up with Dr. Lefkowitz about the possible use of beta blockers to reduce anxiety).[13] *Id.* at 91.

2016-20 Medical Treatment and Testing

The medical records filed in this case (which include treatment events and physician visits, plus testing data, through mid-2020) paint a picture consistent with the records from the late summer—early winter of 2015: J.S. and her family continued to seek emergency and urgent care for symptoms purportedly associated with the HPV or Hep. A vaccine—but which could *themselves* never be shown to reflect some underlying physiologic condition.

Thus, in February 2016, Petitioner underwent heart rate monitoring, but no supraventricular tachycardia or atrial fibrillation/flutter was detected. Ex. 12 at 4. She went back to Riverview Medical Center in early April 2016 with complaints of nausea, vomiting, and abdominal pain, reporting as well that she had a history of POTS and was "immunocompromised" after her receipt of the HPV vaccine, but again no underlying explanation could be found to explain her symptoms or corroborate a vaccine connection. Ex. 13 at 10. Nevertheless, Dr. Lefkowitz (who continued to treat Petitioner) wrote a note (presumably at the request of petitioner or her mother) on June 23, 2016, stating that she had autonomic dysfunction due to the HPV vaccination that was well controlled, and that she could likely return to college. Ex. 12 at 3.

More treatment events occurred in the second half of 2016, but they similarly do not help illuminate the etiology for Petitioner's condition. *See e.g.*, Ex. 15 at 3–4 (visit with endocrinologist in August 2016). Petitioner returned again to a Providence ER in mid-September 2016, reporting symptoms of hyperventilation and intermittent body tremors so severe she had difficulty speaking clearly. Ex. 14 at 1–15, Ex. 29 at 12. Petitioner attributed her symptoms to a POTS occurrence, but her lab work produced normal results, as did a physical exam, with only an EKG revealing some sinus tachycardia. Ex. 14 at 3. She was discharged after her mother arrived at the hospital. *Id.* An ER visit two months later, in mid-November 2016, was comparable in terms of results—discharge despite concerns for "near syncopal episode and tachycardia," which were attributed to missing a medication dose. Ex. 29 at 34.

In the spring of 2017, Petitioner again found herself in the ER in Providence, this time "for tachycardia and questionable seizure." Ex. 29 at 60. Her heartrate was documented as high, in

[13] Beta blockers, also known as beta-adrenergic blocking agents, can be recommended for reducing anxiety, because they inhibit the effects of adrenaline. *See Beta Blockers*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/beta-blockers/art-20044522 (last accessed on June 30, 2022). Beta blockers specifically cause the heart to beat slower, lower blood pressure, and widen veins and arteries. *Id.*

the 150's, and her blood pressure was "fluctuating." *Id*. Petitioner was given Ativan and fluids, which she said helped. *Id.* at 63. Petitioner was advised that she might have "pre-hypertension or hypertension," based on a blood pressure reading, but no other lab testing results revealed a problem other than a possible iron deficiency or somewhat elevated white blood cell count. *Id*. at 85. Upon discharge, the attending physician recommended that she follow-up with her primary care provider to arrange further evaluation for hypertension. *Id.*

Petitioner followed up with Dr. Lefkowitz that October, and he now characterized her presentation as featuring "multiple symptoms that are consistent with massive activation," while also observing that her measured blood pressure levels and heart rate drops were *contrary* to the indicia of POTS. Ex. 33 at 26. An echocardiogram was performed in reaction to Petitioner's claim of "chest pain," and Dr. Lefkowitz wanted her to have an MRI to identify the placement of an intermittent mass that was in or near her heart. *Id*. Dr. Lefkowitz concluded that myxoma[14] might explain some of her presentation. *Id.* at 27. In December 2017, Petitioner wore a Zio patch monitor due to "dizziness and palpitations," but it revealed no notable tachycardia or beat irregularities. Ex. 34 at 1.

There is a two-year gap in the records. Then, in March and April 2019,[15] J.S. sought urgent care for abdominal pain and constipation. Ex. 36 at 4, 8. A CT scan was negative except for "[l]arge fecal loading of the entire colon." *Id*. at 25. In the process of her treatment, Petitioner reported that her mother had informed her that she had a "dysmotility issue related to Gardasil vaccination." *Id*. at 12. The following year (March 2020), Petitioner consulted with a neurologist about a purportedly abnormal MRI (though it is unclear from the record when these results were obtained). Ex. 38 at 12. Dr. Vargas noted that "[s]ince our last visit, [petitioner] had labs which were [within normal limits]." *Id.* A repeat brain MRI was stable in terms of lesions but "did show a tiny 3 mm hypoenhancing focus related to the pituitary gland," leading to a recommendation that a repeat MRI be performed. *Id*. at 15. Lab results were otherwise within normal limits. *Id.* at 12.

Finally, Petitioner has offered some lab test results based on samples taken in April 2020—nearly five years post-vaccination.[16] *See generally* Ex. 37. CellTrend lab results revealed that she tested positive (19.4, normal range < 7.0) for anti a-1-adrenergic antibodies (an antibody often alleged in comparable cases to evidence a mechanistic explanation for dysautonomia). *Id*. But

[14] Myxoma is "a benign tumor composed of primitive connective tissue cells and stroma resembling mesenchyme." *Myxoma,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111236 (last visited July 14, 2022).

[15] Significantly, these records (and indeed *all* medical records filed in this case after August 2016) reflect treatment visits obtained since the claim's initiation.

[16] Petitioner has explained that the purpose of such testing was to support an autoimmune etiology evidenced by elevated norepinephrine levels. Reply at 6–7.

she mostly tested negative after a neuromuscular antibody panel, except for one borderline positive value for IgM vs. neurofacin-155 of unknown significance, although it has been associated with chronic and acute neuropathies with distal weakness, sensory loss, and tremor. *Id.* at 1–2.

II. Expert Reports and Other Evidence

A. *Petitioner's Experts*[17]

Petitioner has offered expert input from two experts—Lawrence Steinman, M.D., Steinman Curriculum Vitae, filed as Ex. 40 (ECF No. 52-1) ("Steinman CV").[18] and Arthur Brawer, M.D., Brawer Curriculum Vitae, filed as Ex. 58 (ECF No. 92-10).[19]

1. Dr. Steinman – Dr. Steinman prepared two reports in support of Petitioner's claim. Report, dated Mar. 2, 2018, filed as Ex. 39 (ECF No. 47-1) ("First Steinman Rep."); Report, dated Jan. 14, 2019, filed as Ex. 86 (ECF No. 85-1) ("Second Steinman Rep."). Dr. Steinman's reports were consistent with what he has offered in many other cases, featuring extensive "cut and paste" sections taken directly from other articles or items of evidence. *See e.g.,* First Steinman Rep. at 4 (attaching in report 2016 antibody testing results from Exhibit 16), 7 (diagram reproduced from *Scientific American* article on how molecular mimicry works).

Dr. Steinman opined that J.S. suffers from "autoimmune dysautonomia with inappropriate tachycardia" caused by her HPV and Hep. A vaccines. First Steinman Rep. at 3. After summarizing her medical history, Dr. Steinman took note of the fact that in 2016 Petitioner had tested positive for certain antibodies to adrenergic and cholinergic receptors. *Id.* at 4–5. He proposed (utilizing the same methodology he has employed in countless Program cases)[20] that

[17] Because my disposition of this case turns on Petitioner's inability to establish any cognizable injury, and because the theories proposed (mostly the HPV vaccine's purported propensity to trigger autoimmune dysfunction) have been the subject of many prior determinations, I am greatly truncating my discussion of expert opinions offered in this case.

[18] Dr. Steinman currently serves as the chairman in immunology and professor in the departments of neurology, pediatrics, and genetics at Stanford University. Steinman CV at 1. He obtained his bachelor's degree from Dartmouth College before earning his medical degree from Harvard University. *Id.* He then completed his internship and residency in surgery, pediatrics, and pediatric and adult neurology at Stanford University. *Id.* He has also completed several fellowships in the area of immunology. *Id.* He is board certified in neurology, though much of his work in the field also involves immunological concepts and theories. *Id.* at 2. However, he has no demonstrated expertise in treating or diagnosing conditions attributable to autonomic dysfunction.

[19] Dr. Brawer has maintained a rheumatology private practice in Long Branch, New Jersey for 44 years. Brawer, Biographical Summary, filed as Ex. 59 (ECF No. 92-11). Previously he obtained his bachelor's degree from Brandeis University and medical degree from Boston University School of Medicine. Brawer CV at 1. He then completed his internship at Genesee Hospital in Rochester, residency at Boston VA Hospital, and fellowship at Boston City Hospital and Boston University Medical Center. *Id.* He is board certified in internal medicine and rheumatology. *Id.* at 2.

[20] Specifically, Dr. Steinman performs a "BLAST" search (meaning Basic Local Alignment Search Tool), permitting him to identify the amino acid identities between vaccine components and the receptors he deemed significant to

via the biologic mechanism of molecular mimicry the two relevant vaccines could result in production of the aforementioned antibodies. *Id.* at 6–15. In effect, Dr. Steinman maintained, antigenic similarity, or homology, between some of the amino acid sequences of proteins in the two vaccines and the relevant adrenergic receptors was sufficient for antibodies produced in reaction the vaccines to mistakenly attack those receptors as well, leading to POTS and/or dysautonomia. *Id.* He allowed that the sequences in question were different for the two vaccines, but added that once immune tolerance was "broken" by one cross-reaction, the process of "epitope spreading" could result in a broadening of the immune response—and hence (in effect) both alleged vaccine-induced cross reactions need not occur for an autoimmune process to set up. *Id.* at 15.

A few other points made by Dr. Steinman in his first report bear on how this case is being resolved. First, he opined that Dr. Lefkowitz's proposed Shay-Drager syndrome diagnosis was not supported by the evidence, since Petitioner "does not have the full manifestations" of it. First Steinman Rep. at 5–6. Second, Dr. Steinman proposed Petitioner's initial experience of "heart racing" within 14 to 15 days of receipt of the first HPV dose was consistent with how long an adaptive immune response resulting in the production of the allegedly-offending autoantibodies would take to occur. *Id.* at 18.

Dr. Steinman's second report reiterated many of his prior arguments, while also taking issue (sometimes to an unnecessarily adversarial degree) with the contentions of Respondent's experts. First, he denied the significance of the fact that the allegedly causal anti-adrenergic receptor antibody could be found in a person without accompanying disease, maintaining (through a wholesale, "cut and paste" reference to his first report) that this fact did not diminish the importance of molecular mimicry's explanatory power. Second Steinman Rep. at 1–4, 14. In so doing, he vouched for his own personal knowledge of the concept over Respondent's expert's comparative lack of publishing history on molecular mimicry. *Id.* at 5–7.

Second, Dr. Steinman disputed the contention that POTS is not usually viewed as an autoimmune illness (although his basis for so arguing relied mostly on narrow readings of what literature was offered in the case on the subject). Second Steinman Rep. at 8-9. Dr. Steinman did, however, highlight literature that discussed a potential autoimmune form of POTS. *Id.* at 9–10; B. Butts, *Human Papillomavirus Vaccine and Postural Orthostatic Tachycardia Syndrome: A Review of Current Literature,* J. Child Neurology 956, 957 (2017), filed as Ex. C, Tab 2 on Feb. 7, 2018 (ECF No. 65-3) ("Butts").[21] He otherwise repeated his contentions about

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Petitioner's injury. This is the precisely same methodologic approach he utilizes in virtually every case in which he offers a causation opinion. *See e.g., A.T. v. Sec'y of Health & Hum. Servs.*, No. 16-393V, 2021 WL 6495241, at *8 (Fed. Cl. Spec. Mstr. Dec. 17, 2021); *Montgomery v. Sec'y of Health & Hum. Servs.*, No. 15-1037V, 2019 WL 2511352, at *5 (Fed. Cl. Spec. Mstr. May 21, 2019).

[21] Also cited as Respondent's Ex. E, Tab 3.

this form of POTS, agreeing that it was not always applicable (even if he did view it relevant to Petitioner). *Id.* at 11. Petitioner had tested positive for the anti-adrenergic antibodies he deemed relevant (albeit only "above the cited upper range of normal"—an "above" level that Respondent's expert observed was minimal) and caused by the HPV or Hep. A vaccine. *Id.* at 12–14. Otherwise, he again argued that the various elements of his molecular mimicry theory were rooted in reliable science, and took some final issue with some of Respondent's diagnostic expert's contentions as well. *Id.* at 15–20.

2. Dr. Brawer – Dr. Brawer prepared three reports in support of Petitioner's claim, one of which was the result of an in-person examination of Petitioner. Report, dated May 3, 2021, filed as Ex. 49 (ECF No. 92-1) ("First Brawer Rep."); Report, dated May 13, 2021, filed as Ex. 60 (ECF No. 93-1) ("Second Brawer Rep."); Report, dated Aug. 16, 2021, filed as Ex. 63 (ECF No. 100-1) ("Third Brawer Rep."). He opined that J.S. suffers from a "Gardasil-induced illness," and found significant the testing results revealing the presence of adrenergic antibodies. However, Petitioner has stated that she is not otherwise relying on the reports he has prepared (*see* Mot. at 3), and therefore I will not further discuss Dr. Brawer's opinions or their bases.[22]

B. *Respondent's Experts*

Respondent offered his own pair of experts: Andrew MacGinnitie, M.D., Ph.D., MacGinnitie Curriculum Vitae, filed as Ex. B (ECF No. 64-8) ("MacGinnitie CV"),[23] and Dr. Peter Bingham, M.D., Bingham Curriculum Vitae, filed as Ex. D (ECF No. 65-9) ("Bingham CV").[24]

[22] Dr. Brawer's final report included a number of unwarranted personal attacks on Respondent's experts, Dr. MacGinnitie and Dr. Bingham. *See e.g.*, Third Brawer Rep. at 3 ("the tone of Dr. Bingham's report suggests that he himself may in part be suffering from a functional neurological disorder"). In reaction, Respondent filed a motion to strike all or part of this supplemental report, but I ultimately denied the motion, explaining in part that the comments resulted in no prejudice against Respondent's experts. ECF Nos. 103, 104. However, I also noted that the fact that the report was replete with this kind of attack only provided me with "a reason for deeming the attacking expert's report to deserve less weight than an even-handed report would receive." ECF No. 104 at 2. Petitioner's decision not to rely on Dr. Brawer's opinions thus had the secondary (and prudent) effect of evading the negative impact of his comments.

[23] Dr. MacGinnitie is currently an attending physician as well as Clinical Director for the Division of Immunology at Boston's Children's Hospital, where he oversees clinical operations for Allergy/Immunology, Rheumatology, and Dermatology. First MacGinnitie Rep. at 1. He obtained his medical degree and Ph.D. in Pathology from the University of Chicago Pritzker School of Medicine. First MacGinnitie Rep. at 1; MacGinnitie CV at 1. Dr. MacGinnitie is board certified in both Allergy/Immunology and Pediatrics and maintains an active clinical practice seeing more than 1,600 patients annually. First MacGinnitie Rep. at 2. He also performs research and has published numerous articles in areas relating to Allergy/Immunology, including vaccine reactions. *Id.*

[24] Dr. Bingham is a clinical researcher and Professor of Neurology & Pediatrics at the University of Vermont. First Bingham Rep. at 1; Bingham CV at 1. He obtained his medical degree from Columbia College of Physicians & Surgeons in New York and completed a fellowship in neuromuscular diseases at The Children's Hospital of Philadelphia. First MacGinnitie Rep. at 1; MacGinnitie CV at 1. Dr. Bingham is board certified in Neurology and Child Neurology and maintained a post-residency experience in general child neurology for 25 years. First Bingham

1. Dr. Bingham – Dr. Bingham prepared two reports for Respondent. Report, dated Feb. 7, 2018, filed as Ex. C (ECF No. 65-1) ("First Bingham Rep."); Report, dated July 19, 2021, filed as Ex. G (ECF No. 99-14) ("Second Bingham Rep."). He opined that there is no reliable medical theory supporting Petitioner's contention that the HPV vaccine can cause POTS.

Dr. Bingham first detailed J.S.'s medical history. First Bingham Rep. at 2–5. He noted that Petitioner's November 18, 2015 tilt table testing showed a pulse rise of 30-40 beats per minute with stable blood pressure, and that the record of the testing itself did not conclude or propose that she in fact could properly be diagnosed with POTS. *Id.* at 5; Ex. 18 at 3. Dr. Bingham was cautious of this diagnosis, because the core symptoms of POTS—chronic, recurrent, orthostatic intolerance—do not otherwise appear in her chart.[25] First Bingham Rep. at 5. But Dr. Bingham acknowledged that the heart rate increase that the test revealed was consistent with POTS. *Id.* He also deemed it "extremely improbable" that Petitioner had Shy-Drager syndrome (which he characterized to be "vanishingly rare"), and hence disputed the legitimacy of Dr. Lefkowitz's diagnosis. *Id.* at 4.

Dr. Bingham next considered the broader category of orthostatic intolerance and where POTS fits within. Orthostatic intolerance generally occurs where a patient experiences "near-fainting" type symptoms (dizziness, palpitations, and graying-out of vision) upon standing. First Bingham Rep. at 6. But because such symptoms often have a subjective quality, a physical exam or tilt table assessment showing a marked pulse rise of over 40 beats per minute (in adolescents) is critical for a reliable POTS diagnosis. *Id.* Dr. Bingham otherwise noted that POTS has a wide array of symptoms and contributing factors (even idiopathic) that all fall under the umbrella of "dysautonomia," or dysfunction in the autonomic nervous system (which regulates a number of bodily functions without conscious effort). *Id.*; G. Heyer, *Postural Tachycardia Syndrome: Diagnosis and Management in Adolescents and Young Adults* Pediatric Annals e145, e146 (2017), filed as Ex. C, Tab 4 on Feb. 7, 2018 (ECF No. 65-5); *Dysautonomia*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15146&searchterm=dysautonomia (last visited July 14, 2022).

Rep. at 1. In the last 5 years, he diagnosed and managed approximately 20 cases each of postural orthostatic tachycardia syndrome, and non-epileptic seizures, in children and adolescents. *Id.* He also has published numerous articles in areas relating to pediatrics and neurology. *Id.* at 1–2.

[25] Dr. Bingham discusses another diagnosis at length—specifically Dr. Brawer's contention that Petitioner suffered from a "Gardasil-induced illness"—and took issue with its legitimacy. Second Bingham Rep. at 2–4.

Additionally, Dr. Bingham argued against Dr. Steinman's supposition that Petitioner's positive alpha 1a adrenergic reception antibodies and the anti-muscarinic antibodies translated to a confirmed POTS diagnosis. *Id.* at 6–7. Dr. Bingham argued that in many cases, individuals without any neurological disease may harbor these antibodies, the tests are not in wide use and have no formal FDA approval, and the rate of background positivity is still unknown. *Id.*

In the context of discussing the causal theory advanced by Dr. Steinman, Dr. Bingham referenced the Institute of Medicine ("IOM") criteria for the strength of evidence relating to causality, noting that these criteria require a combination of epidemiological and biological mechanism data. First Bingham Rep. at 6. But those criteria were absent here. In particular, Dr. Bingham could find no epidemiological evidence of an association between the HPV vaccine and POTS or dysautonomia. *Id.*; J. Arana et al., *Reports of Postural Orthostatic Tachycardia Syndrome After Human Papillomavirus Vaccination in the Vaccine Adverse Event Reporting System,* J. Adolescent Health 577, 581 (2017), filed as Ex. C, Tab 1 on Feb. 7, 2018 (ECF No. 65-2); Butts at 962–63. He also noted that Dr. Steinman's case for biological plausibility attributable to a vaccine-induced cross-reaction was not supported by the results of large-scale studies. *See e.g.,* S. Miranda et al., *Human Papillomavirus Vaccination and Risk of Autoimmune Diseases: A Large Cohort Study of Over 2 Million Young Girls In France*, Vaccine 4761, 4766–67 (2017), filed as Ex. C, Tab 7 on Feb. 7, 2018 (ECF No. 65-8) (assessing two million female patients in a French case-control study, with 37 percent of whom received the HPV vaccine). And he felt that components of Dr. Steinman's molecular mimicry-reliant theory relied heavily on unsubstantiated assumptions, or animal studies not fully comparable to human circumstances. First Bingham Rep. at 7.

Dr. Bingham also maintained that the record in this case did not support the conclusion that the HPV vaccine had likely caused Petitioner's symptoms. Overall, they were simply too non-specific, or more likely the product of anxiety or a psychological issue. First Bingham Rep. at 6–7. Non-epileptic seizures, for example, of the type that Petitioner's neurologists proposed she had experienced are typically presumed psychological in origin and are unlikely sequelae to a vaccine. *Id.* at 6; Second Bingham Rep. at 1–2. Thus, the record did not lend support for the conclusion that her overall post-vaccination symptoms and issues could be attributed to vaccination.

2. Dr. MacGinnitie – Dr. MacGinnitie prepared 3 reports, and commented on what was submitted by both of Petitioner's experts. Report, dated Feb. 7, 2018, filed as Ex. A (ECF No. 63-1) ("First MacGinnitie Rep."); Report, dated June 11, 2018, filed as Ex. E (ECF No. 70-1) ("Second MacGinnitie Rep."); Report, dated July, 19, 2021, filed as Ex. F (ECF No. 99-1) ("Third MacGinnitie Rep.").[26]

Dr. MacGinnitie began with a summary of the medical records, deferring to Dr. Bingham on diagnostic issues. First MacGinnitie Rep. at 2–4. But he devoted the remainder of his report to identifying what he deemed as weaknesses to Dr. Steinman's molecular mimicry theory. First,

[26] Dr. MacGinnitie's third report was focused solely on addressing alleged deficiencies in Dr. Brawer's diagnosis, along with his theory of causation, among other things. Third MacGinnitie Rep. at 1–7. But because Petitioner has opted not to rely on Dr. Brawer's opinion in this case, I do not discuss this aspect of Dr. MacGinnitie's opinion herein.

he asserted there was an overall lack of evidence that POTS and/or dysautonomia are usually or mostly autoimmune-mediated. *Id.* at 4; E. Garland et al., *Postural Tachycardia Syndrome: Beyond Orthostatic Intolerance*, Current Neurology & Neuroscience Rep. 1, 8 (2015), filed as Ex. A, Tab 5 on Feb. 7, 2018 (ECF No. 63-6) (noting that in this study, "only a small number of [POTS] patients were studied and further research is needed to establish clinical significance"); E. Benarroch, *Postural Tachycardia Syndrome: A Heterogeneous And Multifactorial Disorder*, Mayo Clinic Proc. 1214, 1217 (2012), filed as Ex. A, Tab 6 on Feb. 7, 2018 (ECF No. 63-7) ("POTS as the only manifestation . . . of autoimmunity has not been convincingly demonstrated"). Dr. MacGinnitie also pointed out that anti-adrenergic antibodies that Petitioner tested positive for were likely insignificant. Low levels of these antibodies are seen in normal controls, and J.S. did not test positive for a number of other autoantibodies believed associated in some cases with dysautonomia. First MacGinnitie Rep. at 4–6; Ex. 18 at 3.

Second, Dr. MacGinnitie raised several other technical objections to the reliability of the causation theory that vaccination could, via molecular mimicry, provoke an autoimmune response sufficient to cause dysautonomia. First MacGinnitie Rep. at 6–9. Some of the animal models relied upon by Dr. Steinman, for example, were specific to distinguishable conditions involving nerve demyelination, which was not a plausible explanation for POTS or dysautonomia generally. *Id.* at 6. There was also substantial homology in nature that did not result in autoimmune disease. *Id.* at 7–8. And several large epidemiologic studies did not demonstrate any significant incidence of autoimmune diseases after receipt of the HPV vaccine. *Id.* at 8-9; C. Chao et al., *Surveillance of Autoimmune Conditions Following Routine Use of Quadrivalent Human Papillomavirus Vaccine*, J. Internal Med. 194, 193–4, 201–02 (2012), filed as Ex. A, Tab 1 on Feb. 7, 2018 (ECF No. 63-2) (analyzing a database comprised of the medical histories of approximately 189,000 women in California did not confirm association between HPV vaccine and autoimmune disease generally); L. Grimaldi-Bensouda et al., *Autoimmune Disorders and Quadrivalent Human Papillomavirus Vaccination of Young Female Subjects*, J. Internal Med. 398, 404–05 (2014), filed as Ex. A, Tab 4 on Feb. 7, 2018 (ECF No. 63-5) (assessing around 1,800 patients, of which 22 percent received the HPV vaccine, and noting no increased rate of autoimmunity following vaccination).

In his supplemental report, Dr. MacGinnitie reiterated some of his prior contentions, expanding on some points Dr. Steinman had pointedly attempted to critique. He repeated his argument that the common occurrence of homologic similarity between antigens and self protein structures, along with the rarity of autoimmunity generally, undercut the weight to be given solely to a showing of amino acid homologic identity of the kind relied on by Dr. Steinman. Second MacGinnitie Rep. at 1–2. He again emphasized that POTS is largely not thought to be an autoimmune condition, noting that the contrary support associating it with some kinds of autoantibodies is extremely limited in amount or scope. *Id.* at 2–3. He questioned how much

weight could be given to the testing results purporting to show Petitioner's possession of anti-adrenergic antibodies. *Id.* at 3–4. And he observed that Butts (which Dr. Steinman himself cited) only underscored the lack of a relationship between POTS and the HPV vaccine. *Id.* at 5; Butts at 963.

III. Procedural History

The Petition was initiated in August 2016, and at first assigned to different special master. By June of 2017, after the filing of medical records and a substitution of counsel, Respondent filed his Rule 4(c) Report opposing an entitlement award. ECF No. 41. For nearly two years thereafter, the parties filed most of the expert reports as discussed above, and then the case saw no activity for an entire year. In March 2021, however, the case was reassigned to me, and I informed the parties that after some minor additional expert opinions were filed, the matter would be resolved via ruling on the record. Docket Entry Order, dated March 23, 2021. Reports from Dr. Brawer, and supplemental reports from Respondent's experts, were filed through the fall of 2021, and then the parties completed briefing the matter by February 2022. The matter is fully ripe for resolution.

IV. Parties' Respective Arguments

Petitioner argues that she was correctly diagnosed with inappropriate tachycardia based on treating physicians, but mostly bases this contention on Dr. Lefkowitz's October 2015 exam.[27] Mot. at 17, 26; Reply at 7–10. Otherwise, she proposes that she has met her causation-in-fact burden based on the factors established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274 (Fed. Cir. 2005); Mot. at 29–33; Reply at 7–10. Statements from Dr. Steinman, she purports, support her contention that components of the Hep. A and HPV vaccines can elicit immunity to adrenergic receptions, which are associated and cause inappropriate tachycardia and aspects of dysautonomia and POTS via molecular mimicry. Mot. at 30–31; Reply at 8–9. She argues that her T cells were first primed by the Hep. A vaccine and the boosted by the HPV vaccine. *Id.* She links the history of response to the theory of molecular mimicry in the Program as informative—all the while citing to caselaw involving different injuries, but still finding them helpful in her case. *See Morgan v. Sec'y of Health & Hum. Servs.*, No. 15-1137V, 2019 WL 7498665, at *19 (Fed. Cl. Spec. Mstr. Dec. 4, 2019), *review denied, decision aff'd*, 148 Fed. Cl. 454 (2020) (invoking molecular mimicry as a possible explanation for how a vaccine might cause transverse myelitis); *Tarsell v. Sec'y of Health & Hum. Servs.*, No. 10-251V, 2017 WL 4583233, at *6 (Fed. Cl. Spec. Mstr. Sept. 25, 2017), *on remand*, *Tarsell v. United States*, 133 Fed. Cl. 782 (2017) (explaining under the theory of autoimmunity there could be similarities to arrhythmia (alleged in this case) to the claim herein); Mot. at 31–32.

[27] More specifically, Dr. Lefkowitz diagnosed Petitioner with Shy-Drager syndrome, along with apparent generalized autonomic dysfunction resulting in inappropriate sinus tachycardia Ex. 3 at 93, 84.

J.S. next claims that she has demonstrated a logical sequence of cause and effect that the Hep. A and/or HPV vaccines "did cause" her injuries. Mot. at 33–36. First, she points to Dr. Nash, who opined that Petitioner had "a degree of autoimmune encephalopathy provoked by immunizations in a susceptible patient with an autoimmune predisposition." Ex. 4 at 3; Mot at 34. Second, she recounts that as an in-patient at Jersey Shore Hospital she displayed tonic-clonic movements that could be attributable to the HPV vaccination. Ex. 6 at 35, 38; Mot at 34; Reply at 5. She also relies on Dr. Lefkowitz, who initially suspected a vaccine origin to Petitioner's injuries. Ex. 12 at 1, 10–11; Mot. at 34–35. And she denies the alleged tonic-clonic episodes are attributable to psychological stress or anxiety, to warnings on the HPV package insert that they are a known vaccination side-effect. Mot. at 35–36; Reply at 4.

Finally, Petitioner's onset—approximately a day after the HPV vaccine and 15 to 16 days after the Hep. A vaccine—occurred in a post-vaccination, medically-acceptable timeframe, given the HPV package insert warnings as well as the velocity of recall response discussed in the 2012 IOM report. Mot. 36–37. Petitioner also compared her case to that in *Johnson*, arguing that her onset was quicker to manifest, and a better case than those seen before in the Program. Reply at 9; *Johnson v. Sec'y of Health & Hum. Servs.,* No. 14-254V, 2018 WL 2051760, at *22–25 (Fed. Cl. Spec. Mstr. Mar. 23, 2018). Given this evidence and the nature of the theory proposed, Petitioner asserts that a hearing is warranted to permit further inquiry and analysis. Mot. at 38.

In opposing entitlement, Respondent maintains that there is no clear diagnosis of POTS or inappropriate tachychardia, and thus that Petitioner has not identified an "injury" outright. Opp. at 21–23. Otherwise, he argues that the *Althen* prongs have not been satisfied. *Id.* at 23–37. Petitioner has not established that either POTS or inappropriate tachycardia are more likely than not autoimmune, or that specifically anti-adrenergic receptor antibodies likely play a role in causing either. *Id.* at 29–30. Additionally, Respondent finds Dr. Steinman's theory unreliable, as he heavily relies on a mouse model, which does not simply translate to human disease as Dr. Steinman would hope, or BLAST search-confirming homologies that by themselves do not establish likely autoimmune cross-reactivity. *Id.* at 26–27.

Moreover, Respondent maintained, the package insert "admissions" of HPV side effects were undermined by the distinguishable nature of the alleged injury. *Id.* at 36. In particular, the package insert only discusses syncope occurring post-vaccination as "sometimes associated with tonic-clonic movements and other seizure-like activity." Opp. at 36; *see also* Mot. at 35. But Petitioner does not in this case argue (nor does the record show) she experienced syncope—and the same package insert says nothing about autoimmune disease as a recognized side-effect. And there are extensive epidemiological studies that do *not* demonstrate that any of the relevant vaccines are associated with the development of *any* autoimmune diseases. *Id.* at 27–28.

Althen prong two is also unsatisfied, Respondent argues. Petitioner's three instances of treater support are not credible, outweighed by many other instances of treaters stating that the vaccines did not cause her condition. Opp. at 31–35; *see also* Ex. 7 at 67; Ex. 9 at 34, 58; Ex. 28 at 18. Other treaters simply noted a temporal association but did not opine on causation. Opp. at 33. The views of Dr. Lefkowitz were deemed especially unreliable. He diagnosed Petitioner with a self-limiting form of Shy-Drager syndrome that is wholly inconsistent with what is known about it (a neurological disease that usually results in death 6 to 10 months after the inset of symptoms). *Id.* at 32; *The History of Multiple System Atrophy,* The MSA Coalition, https://www.multiplesystematrophy.org/about-msa/history-multiple-system-atrophy-formerly-shy-drager-syndrome-sds/?gclid=EAIaIQobChMIycfvx4So9QIVB7SzCh2YWQtYEAAYASAAEgL1bvD_BwE (last visited July 14, 2022). It was also possible that a viral infection Petitioner picked up while in Central America could have explained some of the autoimmune etiologies embraced (if tentatively at most) by Drs. Lefkowitz or Nash. Opp. at 32–33.

Respondent also deems Petitioner's showing under *Althen* prong three to be insufficient. Several of the Petitioner's symptoms (in particular her tachycardia) were present prior to the receipt of her vaccines. Opp. at 35. And there was no acceptable temporal relationship between vaccination and alleged injury otherwise. Opp. at 36–37. Petitioner's argument on this topic relied heavily on the package insert for the HPV vaccine, and what it says about the possibility of syncope as a reaction - even though (a) syncope is not alleged herein as a symptom, and (b) there is otherwise no evidence that she experienced any true seizure activity (which Dr. Steinman maintained could be "sometimes associated" with syncope). *Id.* at 37. Otherwise, Dr. Steinman's reliance on the 2012 IOM report to support a 14-15 day onset was misguided, since its focus was more on when antibodies would begin to increase in production post-vaccination—not how long it would take for those alleged anti-adrenergic antibodies to begin to cause symptoms manifestation. *Id.*

V. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed.

Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[28] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by

[28] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their

suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed.

Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y of Health & Hum. Servs*., 468 F. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie*, 2005 WL 6117475, at *20. Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy*, 23 Cl. Ct. at 733 (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

There are, however, situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("'[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent'") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything

reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *Lalonde v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the

expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Hum. Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Hum. Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Determining Matter on Record Rather Than at Hearing*

I have opted to decide this case based on written submissions and evidentiary filings, including the numerous expert reports that have been submitted. The Vaccine Act and Rules not

only contemplate but encourage special masters to decide petitions (or components of a claim) on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The Federal Circuit has recently affirmed this practice. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1365–66 (Fed. Cir. 2020). It simply is not the case that every Vaccine Act claim need be resolved by hearing—even where the petitioner explicitly so requests.

ANALYSIS

I. Relevant Decisions Involving POTS and Orthostatic Intolerance Allegedly Attributable to Dysautonomia

POTS is a circulation disorder characterized by a group of symptoms (not including hypotension) that sometimes occur when a person assumes an upright position, including tachycardia, tremulousness, lightheadedness, sweating, and hyperventilation. *Postural orthostatic tachycardia syndrome*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111236 (last visited July 14, 2022). POTS is seen more often in women than in men, and its etiology remains uncertain. *Id.* It implicates the function of the autonomic nervous system, since it involves involuntary physical processes like heart rate.

A tilt table test is often considered the "gold standard" in diagnosing POTS. *Yalacki v. Sec'y of Health & Hum. Servs.*, No. 14-278V, 2019 WL 1061429, at *35 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), *mot. for review den'd,* 146 Fed. Cl. 80 (2019). During the test, the patient is secured on a table while lying flat. John Hopkins Medicine, Health Conditions and Diseases, Postural Orthostatic Tachycardia Syndrome (POTS), https://www.hopkinsmedicine.org/health/conditions-and-diseases/postural-orthostatic-tachycardia-syndrome-pots (last visited July 14, 2022). The table is then raised to an almost upright position. *Id.* The patient's heart rate, blood pressure, and often blood oxygen and exhaled carbon dioxide levels are measured during this test. *Id.* A POTS diagnosis is appropriate if all three of the following criteria are met: (i) the existence of an abnormal, increased heart rate response to being in an upright position; (ii) other symptoms worsen when upright; and (iii) orthostatic hypotension (i.e. a drop in blood pressure) does not develop in the first three minutes of testing. *Id.* A heart rate increase *must* occur in conjunction with a blood pressure drop for the diagnosis to be proper.

This is not the first case in which a petitioner in a case before me has alleged that POTS, or more generally some form of orthostatic intolerance, was vaccine-caused (usually by the HPV

vaccine). But I have never so found.[29] *See e.g.*, *Hughes v. Sec'y of Health & Hum. Servs.*, No. 16-930V, 2021 WL 839092 (Fed. Cl. Spec. Mstr. Jan. 4, 2021), *mot. for review den'd,* 154 Fed. Cl. 640 (2021); *E.S. v. Sec'y of Health & Hum. Servs.*, No. 17-480V, 2020 WL 9076620, at *42 (Fed. Cl. Spec. Mstr. Nov. 13, 2020)*, mot. for review den'd*, 154 Fed. Cl. 149 (2021); *McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451V, 2019 WL 4072113 (Fed. Cl. Spec. Mstr. July 15, 2019); *Yalacki*, 2019 WL 1061429; *Johnson*, 2018 WL 2051760; *Combs v. Sec'y of Health & Hum. Servs.*, No. 14-878V, 2018 WL 1581672 (Fed. Cl. Spec. Mstr. Feb. 15, 2018); *see also Otto v. Sec'y of Health & Hum. Servs.*, No. 16-1144V, 2020 WL 4719285 (Fed. Cl. Spec. Mstr. June 17, 2020) (case dismissed after hearing at claimant's request).

As my prior written decisions state, POTS is most commonly *not* considered attributable to an autoimmune process interfering with the autonomic nervous system. Rather, it is thought to reflect the autonomic system functioning *properly* in response to stressors (for example, hypovolemia, in which a person's dehydrated states produces orthostatic imbalance). *See e.g.*, *McKown*, 2019 WL 4072113 at *52. Moreover, while it is true that some evidence has emerged in the last ten years that in very rare cases POTS might *sometimes* be attributable to an autoimmune process—for example (and as alleged herein) one involving anti-adrenergic antibodies, which can cause heart rate increases—this is the exception to the rule. [30]

Thus, not nearly enough is known about how such an uncommon form of autoimmune-mediated POTS would occur to draw conclusions in Program cases sufficient to meet the preponderance level of evidence. Further, in none of these cases I have decided has it been preponderantly established, through citation to reliable scientific evidence or expert testimony, that the HPV vaccine *itself* could cause the production of anti-adrenergic autoantibodies posited to cause POTS in some limited circumstances. *See e.g.*, *Yalacki,* 2019 WL 1061429, at *20, 31 (while the petitioner was able to offer some reliable literature exploring the possibility that certain POTS cases might be autoimmune-mediated, that evidence did not characterize the likely cause of POTS for the majority of individuals).

[29] It is certainly correct that prior decisions in different cases do not control the outcome herein. *Boatmon*, 941 F.3d at 1358-59; *Hanlon*, 40 Fed. Cl. at 630. But special masters draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs*., 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim") (emphasis added). They would therefore be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions.

[30] In fact, what currently stands as scientific support for this kind of antibody-driven POTS may become further *discredited or rebutted* as time passes. *See e.g.*, *Yalacki,* 2019 WL 1061429, at *18. Arguably, this may already be happening to some degree. In *Yalacki*, for example, Dr. Philip Low (a world-renowned expert at the Mayo Clinic on the autonomic nervous system (whom Dr. Steinman himself favorably cited in his own report in this case (*see* First Steinman Rep. at 5)) noted that he previously had believed that a different kind of autoantibody might be important in causing certain forms of POTS (although in only 10 percent of cases). *Id.* However, subsequent research disproved any correlation to POTS, and he no longer routinely tests POTS patients for particular autoantibodies.

Petitioners have also previously attempted to establish that the HPV vaccine, as well as others, can more broadly stimulate autonomic dysfunction. But the result in such cases has been comparable. *See e.g.*, *America v. Sec'y of Health & Hum. Servs.*, No. 17-542V, 2022 WL 278151, at *27 (Fed. Cl. Spec. Mstr. Jan. 4, 2022) (neurocardiogenic syncope); *E.S.*, 2020 WL 9076620 at *40 (small fiber neuropathy); *K.L. v. Sec'y of Health & Hum. Servs.,* No. 12-312V, 2017 WL 1713110, at *15 (Fed. Cl. Spec. Mstr. Mar. 17, 2017) (seizure and partial onset epilepsy).

I am aware of *no persuasive, well-written decisions* in the Vaccine Program that reach results contrary to any of the above. Nor have I identified the existence of any cases in which a petitioner successfully established that chronic/generalized tachycardia, or an increased heart rate over a period of time long enough to satisfy the Act's six-month severity requirement, was *specifically* vaccine-caused. At most, tachycardia has been a secondary symptom of *other* cognizable injuries. *See* e.g., *Walton v. Sec'y of Dep't of Health & Hum. Servs.*, No. 04-503V, 2007 WL 1467307, at *1 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) ("[petitioner] claimed symptoms of 'fever, chest pain, nausea, headaches, dizziness, lightheadedness, racing heart rate, tired feeling, faintness, Coxsackie-carditis with *supra-ventricular tachycardia* with pronounced exhaustion pathology[]' . . . .") (emphasis added).

II. Petitioner Has Not Demonstrated a Cognizable Vaccine Injury

As reasoned Program case law instructs, a petitioner's claim is premised on first establishing the underlying *existence* of an injury that could be attributable to a prior vaccination. An inability to establish an injury by preponderant evidence can be fatal to a claim. *Broekelschen*, 618 F.3d at 1346, 1349. It is thus often necessary at the outset of analyzing a petition to determine whether a given alleged injury has been preponderantly established in the first place. *Locane v. Sec'y of Health & Hum. Servs.,* 685 F.3d 1375, 1381 n.3 (Fed. Cir. 2012); *Lombardi v. Sec'y of Health & Hum. Servs.,* 656 F.3d 1343, 1353 (Fed. Cir. 2011).

This case features a lengthy, ample medical record that strongly establishes that Petitioner regularly sought medical treatment, often on an emergency basis, after her vaccinations in 2015.[31] Indeed, in the month after vaccination, she was treated at an ER four times alone. And she did so because of a series of panic attack-like episodes that were accompanied by a feeling of a racing heartbeat. But that record simply does not preponderantly establish any actual *injury* that could be grounds for a Program claim.

First, and most significantly, the alleged POTS injury—unquestionably a debilitating medical condition, regardless of whether it can be vaccine-caused—has not been preponderantly established. J.S. was never legitimately diagnosed with POTS. Initial testing of Petitioner's heart

[31] Petitioner's sister also filed a case in the Program alleging similar symptoms but was denied entitlement. *E.S.*, 2020 WL 9076620 at *6, n.21.

rate and blood pressure levels were inconsistent with it. The subsequent, thorough tilt-table test she underwent in November 2015 did not formally confirm the diagnosis either, even if some elements of it (in particular an increased heart rate) were suggestive of it. Ex. 18 at 3. The record of this testing event is facially thorough. And no subsequent testing evidence has been filed that would confirm the diagnosis. At most, Respondent's expert Dr. Bingham allowed the *possibility* that the November testing could support POTS—but that is not the same as an admission (consistent with the preponderant standard applicable herein) that it was *likely*.

Second (and without taking anything away from the feelings of distress that caused Petitioner to seek treatment so regularly), Petitioner's other reported symptoms—whether characterized as "inappropriate tachycardia"[32] or something else—do not, individually or collectively, amount to a cognizable condition of any kind that could be shown to be vaccine-caused. As observed by Dr. Bingham, her symptoms were consistently non-specific. They are also transient/intermittent—and this is especially true of the purported "inappropriate tachycardia." Thus, while there are instances in which Petitioner displays an increased heart rate on exam, she does not consistently do so, and other autonomic testing (performed at the same time as the tilt table test) did not identify measurable orthostatic intolerance. Ex. 18 at 1–3. Again, while Petitioner might have *displayed* occasions of post-vaccination tachycardia at times in this record, it cannot be deemed to be a persistent condition that could reasonably be linked to vaccination.

Contentions that Petitioner experienced syncope-associated "clonic-tonic" seizures are especially spurious. The record plainly establishes that her treaters from the fall of 2015 (who saw Petitioner in the immediate wake of claimed episodes) consistently deemed her movements to be pseudoseizures, and attributed related symptoms to an unidentified underlying psychological condition. *See e.g.*, Ex. 6 at 4, 38, 40, 42, 80, 130-31, 134; Ex. 7 at 66-67, 89-90, 223, 233-36; Ex. 9 at 71. No formal medical testing ever later confirmed the presence of any epileptic etiology or factors that might cause seizure activity—and in fact the absence of such evidence was clear not long after the relevant vaccinations. *See e.g.*, Ex. 9 at 64-68 (September 2015 neurologic evaluation and EEG results).[33] And MRI results were largely nonspecific as well—certainly none confirmed the kind of brain abnormalities that might explain seizure etiology.

The only potentially-reliable evidence supporting the finding that Petitioner might have

[32] As Respondent persuasively points out, it is not self-evident that (at least from Dr. Steinman's perspective) "inappropriate tachycardia" is a condition distinguishable from POTS. Opp. at 21-22 (citing First Steinman Rep. at 18 (alleging that the anti-adrenergic receptor antibodies are "associated with autoimmune dysautonomia, *sometimes referred to as POTS*") (emphasis added).

[33] Even Dr. Lefkowitz agreed. *See* Ex. 12 at 11 ("I believe that we have shown that the tonic-clonic movements are unrelated to seizure activity based upon the video EEG").

had some kind of cognizable injury comes from Dr Lefkowitz.[34] But there are numerous reasons to give his opinion little weight—aside from the oft-noted Program admonition that treater views are never *per se* sacrosanct or dispositive. *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009). First, Dr. Lefkowitz's proposal that Petitioner might have Shy-Drager syndrome was not only not accepted by both side's experts, but later was largely abandoned by Dr. Lefkowitz himself (since he does not appear to have maintained or refined this initial speculation in his exams of Petitioner in later years). *See e.g.,* Ex. 33 at 27 (concluding that Petitioner may have myxoma during a follow-up in October 2017); First Bingham Rep. at 4 (disputing Dr. Lefkowitz's diagnosis as Shy-Drager has become "vanishingly rare," and Petitioner's tests were not consistent with such a diagnosis); First Steinman Rep. at 5 (observing that Petitioner does not have the full manifestations of Shy Drager syndrome). This peculiar diagnosis alone somewhat discredits his judgment, since it is an outlier view that no other treater ever echoed or adopted.

Second, the overall evidentiary record is inconsistent with the conclusion that Petitioner's symptoms were anything more than temporally related to vaccination. When evaluating disputes about a claimant's medical condition, it is critical to consider the *overall* medical history in its totality. What one treater is told, or understands, about a claimant's history at a certain point in time can be incomplete, or reflect a tentative, initial diagnostic proposal that later on is not confirmed by subsequent testing or the course of the injured party's medical disease. Here, Dr. Lefkowitz not only appears to have relied heavily on Petitioner's self-reported history (which did not emphasize the extent to which her prior multiple ER visits never corroborated an underlying physiologic explanation for her episodes), but he evaluated her in early October 2015 - *before* the negative tilt-table test conducted the next month. His opinions about her injury (and its association with HPV vaccine) seem ultimately speculative, and are in any event unsubstantiated by the record.

The medical record also contains numerous, credible instances in which treaters proposed or surmised that Petitioner's symptoms had a psychologic component, reflecting either somatization, excessive anxiety, or some other mental trauma that precipitated a heightened heart rate and other panic-like symptoms. *See e.g.*, Ex. 6 at 80 (August 21, 2018 visit with treaters finding the Petitioner experienced a pseudoseizure); Ex. 7 at 36 (August 23, 2015 neurology consult diagnosing petitioner with acute anxiety disorder); Ex. 9 at 47 (September 22, 2015 neurology evaluation discussing recent stressors in petitioner's life that may have caused her seizure-like activity); Ex. 13 at 213 (September 19, 2015 neurology consultation with a clinical impression of "probable pseudo-seizures", "stress related psycho-somatization or somatization", and "probable anxiety associated panic"). As a special master, I am certainly not

[34] Although Dr. Nash's infectious evaluation seemed to allow for a possible autoimmune injury, he more expressly discounted dysautonomia, noting that Petitioner displayed only "minor orthostatic changes which are not consistent with POTS or significant autonomic instability." Ex. 4 at 3.

called upon to offer a diagnosis of my own (and am far from qualified to do so in any event). But there are enough instances established in the record simply from the fall of 2015, in which on-the-scene treaters offered such an opinion. The possibility of a psychological factor as causal of Petitioner's symptoms also strongly negates the conclusion that Petitioner did in fact experience something that reasonably could be seen a potential vaccine injury.

I give little weight to the testing results Petitioner obtained in 2020—almost five years after her vaccination, and nearly four years after the case was filed—suggesting she possessed certain anti-adrenergic autoantibodies theorized to cause dysautonomia. Assuming the results of this test are even reliable,[35] it cannot be determined on this record that she possessed these specific antibodies *in the immediate one to ten days after receipt of the HPV vaccine*, when her tachycardia is alleged to have begun, and it is highly speculative to assume otherwise. There is simply no record evidence in this case that Petitioner possessed these antibodies in the fall of 2015. These results thus do not add any legitimate weight to the contention that Petitioner did in fact experience an actual injury post-vaccination.

Given all of the foregoing, I cannot conclude from this medical record that Petitioner "more likely than not" experienced *any* cognizable illness or injury that could be attributed to vaccination in any manner other than temporally (an insufficient basis for entitlement, as well-recognized in the Program). *Bunting*, 931 F.2d at 873. Without an injury, this case cannot proceed.

II. Petitioner's Causation Theory is Unreliable and/or not Preponderantly Supported by the Evidence

I need not engage in an *Althen* causation analysis under the circumstances. *See e.g., Lasnetski v. Sec'y of Health & Hum. Servs.*, 128 Fed. Cl. 242, 264 (2016) (no error for special master to forgo *Althen* analysis after determining that a petitioner had not in fact experienced the disease or illness alleged to have been vaccine-caused), *citing Hibbard*, 698 F.3d at 1365. I acknowledge, however, that the record does contain post-vaccination instances in which Petitioner displayed transient tachycardia, and the scattered occurrences of this over time *might* be enough to be deemed an injury of sorts. Could this condition be vaccine-caused? The theory offered by Petitioner was not reliably-established—and is otherwise unpersuasive.

As noted above, I have repeatedly encountered the argument that the HPV vaccine[36] can

[35] Although my decision does not turn on the reliability of these specific testing results, Dr. MacGinnitie raised reasonable objections to their trustworthiness. *See e.g.,* First MacGinnitie Rep. at 4–5; Second MacGinnitie Rep. at 3–4.

[36] Although Petitioner also asserts the Hep. A vaccine was causal, her focus is on the HPV vaccine—and I do not otherwise find that evidence specific to the Hep. A vaccine offered in this case was any more persuasive or preponderant on the question.

result in the production of autoantibodies sufficient to cause POTS through an autoimmune process—more often than not alleged to interfere with certain adrenergic nerve receptors. Dr. Steinman has offered an expert opinion to this end in many such cases. *See e.g.*, *E.S.*, 2020 WL 9076620 at *10–14. But time and again, I have deemed the theory wanting, either because (a) it was not reliably shown that the vaccine could likely trigger the production of offending autoantibodies, or (b) the claimant's injury was not established to fall into the narrow category of autoimmune-driven POTS (which is almost exclusively *not* an autoimmune condition). *Id.* at 44, 50.

Against this backdrop, nothing offered in this case by Petitioner or her experts provides more recent or more reliable evidence supporting the conclusion that the HPV vaccine might cause POTS (or any associated autonomic-associated symptoms for that matter). On the contrary, the theory offered is no different than what I have been presented with before.

Dr. Steinman, for example, makes the same literal arguments about theoretical homology between components of the HPV vaccine and nerve receptors that are always presented in such cases—but with insufficient reliable corroborative proof supporting the conclusion that the homology is *meaningful* from a pathogenic sense. Merely showing via BLAST searches that some homology exists between amino acid sequences in the HPV vaccine components and nerve cells does not amount to a preponderant showing that the vaccine can produce antibodies that will likely cross-react against those cells. Establishing the existence of potential homology based on internet-driven research performed solely for this case is thus not enough to meet the preponderant burden of establishing it more likely than not that the vaccine *would* cross-react as proposed. *Sullivan v. Sec'y of Health & Hum. Servs.*, No. 10-398V, 2015 WL 1404957, at *17–18, n.30 (Fed. Cl. Spec. Mstr. Feb. 13, 2015) (while the law does not require Petitioner to "prove" homology in a Program case, mere assertion that HPV strain shares sequences with human body such that molecular mimicry might occur resulting in injury was by itself insufficient to satisfy burden). Indeed, as Dr. MacGinnitie noted, amino acid sequential/component homologies are easily demonstrated in nature, but their presence does not also mean concurrent cross-reactivity is inevitable. First MacGinnitie Rep. at 4. Even Dr. Steinman so concedes. First Steinman Rep. at 15.

Arguments about the autoimmune character of POTS, or the possibility that the HPV Vaccine could encourage the production of autoantibodies thought to be POTS-associated, were also unreliably established. It remains true that the majority of cases of POTS are likely *not* mediated by an autoimmune process. It has not been otherwise persuasively shown that the HPV or Hepatitis A vaccines are likely to cause production of the proposed antibodies in any event (which Petitioner did not even test positive for until years after vaccination). And Respondent's experts persuasively established that the vaccines at issue were highly *unlikely* to cause POTS specifically or orthostatic intolerance generally. All of the above precludes me from determining that the "can cause" prong has been met.

The contention that the HPV vaccine could be associated with "clonic-tonic" seizures or comparable movements is also thin from a scientific reliability perspective. This purported association largely (if not wholly) is derived from the HPV vaccine package insert. *See* First Steinman Rep. at 17. Putting aside the fact that package inserts are not deemed in the Program to be particularly probative evidence for injury causation,[37] the quoted portion by its own terms reads as specific to syncope, which would typically occur *close-in-time* to vaccination. *Id.* ("observation for 15 minutes *after administration* is recommended") (emphasis added). It cannot be reasonably read to suggest that the HPV vaccine is associated with a persistent risk of syncope.

Moreover, there is no evidence at all of a close-in-time syncopal event, with no arguable reaction to the HPV vaccine until a full day later. Ex. 7 at 211-13. And any purported jerking or seizure-like movements in the days following vaccination were not deemed legitimate seizure activity by any treaters Petitioner saw (regardless of Petitioner's assertions to the contrary). Petitioner otherwise seeks to select isolated instances from the record where a syncopal-like blood pressure drop can be shown to have temporally-occurred when a "shaking episode" purportedly occurred (*See e.g.*, Mot. at 7 (highlighting blood pressure reading taken immediately prior to seizure-like episode)). But the package insert reference cannot be leveraged into a persuasive causal theory based on this kind of incident—especially since the overall record (a) does not corroborate POTS, (b) does not contain a diagnosis of syncope, and (c) ultimately preponderates against a finding that Petitioner routinely suffered from similar "shaking episodes."

Admittedly, my analysis of Petitioner's causation showing in this case is more cursory than what I would deem necessary in other contexts. I could easily go into the "weeds" on the points made by Dr. Steinman about homology and the possible autoimmune mechanisms by which any vaccine might trigger disease. But as noted above, I have *repeatedly* had the occasion to consider whether medical science establishes an association between the HPV vaccine and a variety of dysautonomic reactions, including POTS specifically or orthostatic intolerance more generally. The same kinds of arguments made in those cases are offered herein—and they were no more persuasive simply through their repetition. This is yet another case where Dr. Steinman has been enlisted to offer a molecular biology-heavy opinion about homology and a potential for cross-reactivity, but without sufficient reliable evidence to connect the various sub-components of his theory. And no reliable scientific or medical evidence was offered that would suggest my prior determinations should be revisited. As a result, a granular discussion of the deficiencies in Petitioner's causation argument would be inefficient,[38] and end up repeating what I have now said

[37] *See Zumwalt on behalf of L.Z. v. Sec'y of Health & Hum. Servs.*, No. 16-994V, 2019 WL 1953739, at *17 (Fed. Cl. Spec. Mstr. Mar. 21, 2019), *review denied, decision aff'd sub nom. Zumwalt v. Sec'y of Health & Hum. Servs.*, 146 Fed. Cl. 525 (2019) (". . . package inserts are generally afforded very little weight in Vaccine Program cases as proof of causation.").

[38] My determination—not to belabor in great detail the deficiencies with Petitioner's causation theory—is in part the

multiple times about HPV vaccine, POTS, and dysautonomia generally.

III. Petitioner's Condition Has a More Likely Alternative Cause

A related reason for rejecting this claim arises from the fact that the same record that undermines the existence of any possibly vaccine-caused injury provides a credible and persuasive alternative explanation for Petitioner's symptoms. Although "alternative cause" is understood to be a burden placed on Respondent, special masters are not prevented from taking into account this kind of evidence when evaluating whether a petitioner has met her *Althen* burdens. *Stone v. Sec'y of Health & Human Servs*., 676 F.3d 1373, 1380 (Fed. Cir. 2012) ("no evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute"); *de Bazan*, 539 F.3d at 1353 ("[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief"); *see also Inamdar v. Sec'y of Health & Hum. Servs.,* No. 15-1173V, 2019 WL 1160341, at *19, n.13 (Fed. Cl. Spec. Mstr. Feb. 8, 2019) (the burden of proof does not shift to Respondent to prove an alternative cause *until* a petitioner carries his initial burden of proof).[39]

Here, the record is replete with such evidence. For the medical records filed in this case reliably suggest that Petitioner's symptoms were more likely attributable to somatization or some anxiety condition, rather than an independent illness, vaccine-caused or not. *See e.g.,* Ex. 7 at 224, 226–27, 233 (August 20, 2015 ER visit complaining of anxiety, hyperventilation, and a panic attack); Ex. 9 at 47 (September 22, 2015 neurology evaluation noting the recent stressors in petitioner's life may have caused seizure-like activity); Ex. 13 at 213 (September 19, 2015 neurology consultation stating the clinical impression is "probable pseudo-seizures", "stress related psycho-somatization or somatization", and "probable anxiety associated panic"). Petitioner certainly has provided no reason for me to discount the numerous treater opinions (most of which come close in time to vaccination, and were never subsequently rejected) that her non-specific symptoms were not attributable to disease or vaccination.

product of the crushing caseload that burdens the Vaccine Program. Wise management of judicial resources counsels against penning 100-page decisions in every disputed Vaccine Act case—especially when, as here, the case presents theories that a special master has demonstrated experience addressing.

[39] Given the record in this case, I would be able to find that Respondent *had* preponderantly established an alternative cause for Petitioner's symptoms *even* if the burden had shifted (which I do not find occurred).

IV. This Claim was Properly Resolved Without a Hearing

In ruling on the record, I am opting against holding a hearing, over Petitioner's objections. The choice of how best to resolve this case is a matter that lies generally within my discretion, but because Petitioner challenges this manner of disposition, I shall explain my reasoning.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to afford each party a "full and fair opportunity to present its case." *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Hovey*, 38 Fed. Cl. at 401; *see also Kreizenbeck,* 945 F.3d at 1366. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not *itself* grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

In this case, no hearing was required to resolve fairly Petitioner's claim. I was able to evaluate the evidentiary strength of her asserted injury through a close review of the medical record. That record overwhelmingly undermines the contention that vaccination harmed Petitioner. Instead, preponderant evidence strongly supports the conclusion that some other kind of mental disorder explains her symptoms. All of these matters were self-evident from a careful review of the record itself, and did not require a hearing for their complete explication.

The fact that multiple numerous expert reports on both sides were filed is also not a compelling reason to hold a hearing. Petitioner's decision not to rely on Dr. Brawer's opinions in fact limited the number of reports in contention. Moreover, the experts at issue (in particular, Drs. Steinman and MacGinnitie) have testified before me multiple times. And I am extremely familiar with Dr. Steinman's arguments about molecular mimicry as an explanation for autoimmunity, as well as the broader theory that the HPV vaccine can cause POTS.

Thus, nothing presented by these experts was so complex that I needed to hear their live testimony. And complexity is never a *per se* justification for a hearing in any event. Indeed, I have resolved by ruling on the record science-dense cases in which both sides made credible, reasonably-contested arguments arising from multiple expert reports. *See e.g.*, *D'Toile,* 2016 WL 7664475.[40] I was able to resolve the disputed issues in such cases, which were fairly disputed, without live witness testimony. At bottom, my decision to rule without hearing reflects my

[40] By contrast, I have also dismissed cases like this one, where the filing of multiple reports masked what was determined to be a wholly unreliable claim. *Kreizenbeck*, 945 F.3d at 1365–66 (dismissing on record case in which parties together offered opinions from six experts in total; petitioner attempted to convert abandoned autism injury claim into assertion that vaccines precipitated encephalopathic reaction resulting in developmental regression).

reasoned determination (especially after hearing many comparable claims that the HPV vaccine can cause POTS or some other forms of dysautonomia) that this record simply does not permit the conclusion that vaccination had anything to do with J.S.'s symptoms.

V. Comment on Program Viability of HPV/Dysautonomia Vaccine Injury Claims

As of the present date, *I have never ruled that the HPV vaccine likely causes any form of dysautonomia.* The medical science that has been offered on this contention in case after case simply does not support that conclusion—and I am aware of no counter, persuasive analyses that would suggest the alternative. I have thus decided enough cases involving HPV vaccines and allegations of dysautonomia to recognize the inherent weakness of such a claim from the start of the case's initiation. These claims reflect merely a (literal) temporal "coincidence" between vaccination and onset—something well recognized to not support causation. *Grant,* 956 F.2d at 1148. While it remains possible that medical science may someday reach more reliable conclusions about this subject matter that would present an occasion for reconsideration of my current conclusions, that day has yet to come.

In the future, Program petitioners and their counsel *must avoid bringing claims involving the HPV vaccine and allegations of dysautonomia* if they wish to receive fees.[41]

CONCLUSION

J.S. may have experienced a number of overlapping symptoms and conditions over many years that have caused her and her family considerable anguish—in their efforts to treat as well as to identify some unifying explanation for her constant need for medical care. She also no doubt has a good faith belief that the HPV and flu vaccines had to have some relationship to her

[41] I also emphasize that I find that ***this particular case lacks reasonable basis going forward***. *See Heath v. Sec'y of Health & Hum. Servs.*, No. 19-749V, 2020 WL 7869438, at *2 (Fed. Cl. Spec. Mstr. Nov. 16, 2020) ("The standard for reasonable basis is lesser (and inherently easier to satisfy) than the preponderant standard applied when assessing entitlement, as cases with reasonable basis (because they have objective proof supporting the claim) can nevertheless still fail to establish causation-in-fact.") (citing *Braun v. Sec'y of Health & Human Servs.,* 144 Fed. Cl. 72, 77 (Fed. Cl. 2019)); *see generally E.S. v. Sec'y of Health & Hum. Servs.*, No. 17-480V, 2021 WL 5816006, at *5 (Fed. Cl. Spec. Mstr. Nov. 10, 2021) (warning counsel that I shall be more inclined to deny attorney's fees in the future for HPV and allegations of dysautonomia in cases that do not present any new or more reliable scientific or medical evidence to support the claim—however, I would note that the case herein was filed before this fee's decision).

Even if some objective evidence supported the claim at the time of its initiation, I have now concluded that no reliable science supports Petitioner's contentions, and therefore it can no longer be reasonably contended that Petitioner's prior symptoms are "objective" support for the claim. As a result, counsel acts at his own risk if he opts to extend this claim's life further, such as through unnecessary motions for review or additional appeals. I will not award any fees incurred for such work (although I am prepared to award fees reasonably devoted to the claim's prosecution up to this point).

injuries—if for no other reason than the increased tempo of her symptoms post-dated her receipt of the vaccines.

Nevertheless, the overall picture painted herein by the objective medical record is unsupportive of the conclusion that the HPV and Hep. A vaccines were causal of any of her post-vaccination symptoms, despite their complex array and convoluted progression. Nor, more fundamentally, do those symptoms add up to a discernible injury. The deficiencies of this claim were self-evident enough that a hearing was not required to adjudicate the matter.

Accordingly, for the reasons set forth above, I deny compensation in this case and dismiss the matter. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.[42]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[42] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.